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# Formulation and Physicochemical Characterization of a Nanostructured Lipid Carrier (NLC) Gel Combining Minoxidil and Finasteride for the Treatment of Alopecia in Prospective Hajj Pilgrims

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## ABSTRACT

Nanostructured Lipid Carriers (NLCs) are innovative lipid-based delivery systems used in topical applications to dissolve active ingredients within the oil phase. Minoxidil functions as a vasodilator that stimulates hair growth, while Finasteride is a specific inhibitor of type II 5α-reductase, proven effective in treating androgenic alopecia. The combination of these two active ingredients in an NLC system offers an efficient strategy to enhance bioavailability, improve stability, and increase comfort in topical use. This study aims to develop an NLC gel formulation containing both Minoxidil and Finasteride as a potential treatment for androgenic alopecia, particularly in prospective Hajj pilgrims who are susceptible to hair loss due to extreme environmental conditions. The formulation incorporates solid lipid monostearin and liquid lipid Miglyol 808 at an 8:2 ratio, with Carbopol 940 as the gel base. Physicochemical evaluations including particle size, pH, viscosity, entrapment efficiency, and spreadability were conducted to assess formulation stability and performance. The results indicated that the formulation met the desired criteria, with particle size <1000 nm, pH ranging from 5.5 to 6.0, entrapment efficiency >80%, and optimal spreadability. This NLC gel presents a practical and effective alternative for managing hair loss, especially under extreme conditions.

**Keywords:** nanostructured lipid carrier; minoxidil; finasteride; alopecia; hajj-bound pilgrims

## INTRODUCTION

Alopecia is a medical condition characterized by hair loss, affecting either localized areas or the entire body, predominantly the scalp. Its development can be attributed to a range of intrinsic factors, including genetic predisposition, hormonal imbalances, systemic diseases, nutritional deficiencies, and exposure to toxins. Furthermore, extrinsic elements such as environmental stressors and the use of unsuitable hair care products can further compromise follicle health, thereby impeding hair growth (1). Beyond its physical manifestations, alopecia can also induce psychological distress, frequently resulting in diminished self-esteem among affected individuals (2).

Among the various types of alopecia, androgenetic alopecia (AGA) is the most prevalent, affecting over 70% of adult men and nearly 50% of women, with the highest incidence observed in Caucasian males between the ages of 20 and 30 years (3). In Indonesia, precise epidemiological data on AGA prevalence remain limited due to a paucity of research and low public awareness regarding effective treatments. This condition holds particular relevance for prospective Hajj pilgrims. Optimal physical health is crucial during the pilgrimage. Prolonged exposure to intense sunlight, elevated temperatures, and the continuous wearing of head coverings may exacerbate hair loss. Moreover, the physical and psychological stress experienced throughout the preparation for and the duration of the pilgrimage itself can accelerate the progression of AGA. Appropriate management not only enhances self-confidence but also protects scalp health against adverse environmental conditions.

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The management of AGA involves both topical and systemic approaches. Topically, minoxidil is a recognized effective treatment. Systemically, finasteride is used to inhibit the miniaturization of hair follicles by blocking the conversion of testosterone to dihydrotestosterone (DHT) (3). However, both therapies have limitations, including side effects such as skin irritation with minoxidil and sexual dysfunction with finasteride (4). Combining topical minoxidil and finasteride has demonstrated superior efficacy compared to monotherapy, resulting in significant improvements in hair coverage and patient satisfaction (5).

Not all drugs possess the physicochemical properties necessary for effective topical application, including low molecular weight, lipophilicity (Log P around 2), and a low melting point (below 93.33ºC). Consequently, the efficacy of topical drugs is significantly influenced by the characteristics of both the active compounds and the carrier systems employed. A modern carrier innovation that enhances the effectiveness of topical drugs is the Nanostructured Lipid Carrier (NLC) system (6). The lipid composition within the NLC system significantly influences its properties and its effectiveness as a carrier for active ingredients (7). Research has demonstrated that a combination of solid lipid monostearin and liquid lipid Miglyol 808 at an 8:2 ratio yields optimal results. This specific combination enhances stability, drug entrapment capacity, and release control, exhibiting favorable physicochemical characteristics and a high release flux, as evidenced in NLC meloxicam formulations (8).

The liquid form of NLC presents limitations for topical application and thus necessitates its incorporation into semi-solid bases such as gels, ointments, or creams, utilizing polymers like carbopol, cellulose derivatives, or poloxamer (6). Among these semi-solid bases, gels are considered superior due to their viscoelasticity, flexibility, high absorbency, softness, and favorable spreadability. Furthermore, their hydrophilic nature renders gels comfortable upon application, non-greasy, easily spreadable, and readily removable (9).

This study employs a combination of solid lipid monostearin and liquid lipid Miglyol 808 at an 8:2 ratio within the NLC system as the carrier for minoxidil and finasteride. To improve viscosity, stability, and application comfort, carbopol 940 was selected as the gelling agent (10). Therefore, this study aims to develop an NLC gel formulation incorporating minoxidil and finasteride with optimal physicochemical characteristics, including particle size, a stable pH range of 5.0 to 6.5, a gel viscosity ranging from 2000 to 4000 cPs, high entrapment efficiency, and a spreadability range of 5 to 7 cm. This formulation is anticipated to offer a more effective, practical, and safe alternative therapy for androgenic alopecia, thereby improving patients' quality of life.

## METHODS

### Tool

The equipment utilized in this study included an analytical balance (Shimadzu ATX224), a hot plate (Heidolph), a magnetic stirrer (Nuova stirrer), a digital pH meter (Mettler Toledo SevenDirect SD20), a cone and plate viscometer (Brookfield, USA – DV3TLVCJ0), a 'Rion' Viscotester VT-04F, a Particle Size Analyzer (Microtrac Nanotrac wave II), a UV-Vis spectrophotometer (1800 Shimadzu), an ultra-turrax homogenizer (IKA T25), a centrifuge (Hettich EBA 200), a set of glassware (Iwaki), a mortar, and a pestle.

### Materials

The materials utilized in this study were all of pharmaceutical grade. The Nanostructured Lipid Carrier (NLC) gel formulation consisted of the following components: Minoxidil, Finasteride, Monostearin (Sigma Aldrich), Miglyol 808 (Sigma Aldrich), Tween 80 (Merck), Carbopol 940 (Merck), Propylene glycol, Methylparaben (PT Brataco), Propylparaben (PT Brataco), Na-EDTA (Merck), Triethanolamine (Merck), and phosphate buffer pH 6 ± 0.05 prepared from Na2HPO4 (Merck) and NaH2PO4 (Merck).

### Detailed Procedure

In this study, the preparation of the minoxidil and finasteride combination NLC formulation was conducted in triplicate, with each batch weighing 100 grams. The specific formulation is detailed in Table 1. The emulsification

technique was employed for the preparation. The NLC system synthesis commenced with melting the lipid phase (monostearin and Miglyol 808) at an 8:2 ratio, along with the active pharmaceutical ingredients, minoxidil (5% w/w) and finasteride (0.25% w/w), at 65°C, which is above the melting point range of the solid lipid (55–60°C). Concurrently, the aqueous surfactant solution of Tween-80 (5% w/w) and the phosphate buffer with a pH of 6.0 ± 0.05 were heated to the same temperature. Subsequently, the heated aqueous phase was dispersed into the hot lipid phase using an ultra-turrax homogenizer at a speed of 3400 rpm for 30 minutes. Following homogenization, the resulting emulsion was cooled and stirred using a magnetic stirrer at 100 rpm until the temperature reached 25°C, after which the final weight of the NLC dispersion was recorded (8).

**Table 1. Formulation of Minoxidil and Finasteride Combination NLC**

| No. | Material | Function | Concentration (% w/w) |
|---|---|---|---|
| 1. | Minoxidil | Active ingredient | 5 |
| 2. | Finasteride | Active ingredient | 0.25 |
| 3. | Monostearin | Solid lipid | 8 |
| 4. | Miglyol 808 | Liquid oil | 2 |
| 5. | Tween 80 | Surfactan | 5 |
| 6. | Dapar fosfat pH 6 ± 0,05 | *Buffer* | ad 100 |

**Gel Base Preparation**

The gel base was prepared according to the formula outlined in Table 2. Carbopol 940 was dispersed in carbon dioxide-free water at a ratio of 25 parts water to 1 part Carbopol 940 and triturated until completely mixed. Subsequently, triethanolamine (TEA) was added dropwise until the pH reached 5.5–6.0, and the mixture was stirred until a gel formed. In a separate container, methylparaben and propylparaben were dissolved in propylene glycol, while sodium ethylenediaminetetraacetic acid (Na-EDTA) was dissolved in water. These solutions were then incorporated into the gel base and stirred until homogeneous. Finally, the remaining water was added, and the entire mixture was stirred until complete homogeneity was achieved.

**Preparation of Minoxidil and Finasteride Combination NLC Gel**

The minoxidil and finasteride combination NLC gel was prepared in a total quantity of 100 grams by weighing 50 grams of the NLC dispersion and 50 grams of the gel base separately. Subsequently, the NLC dispersion was dispersed into the gel base while stirring using a magnetic stirrer at a speed of 200 rpm for 15 minutes.

**Physicochemical Characterization of Minoxidil and Finasteride Combination NLC Gel**

**Organoleptic Evaluation**

Organoleptic evaluation was performed using human sensory perception. This testing involved the assessment of color, aroma, and consistency of the test samples. Gel formulations typically exhibit a clear appearance with a semi-solid consistency (11).

**pH Measurement**

The pH measurement was conducted using a calibrated pH meter. Ten milliliters of the Minoxidil and Finasteride combination NLC gel system were taken, and the electrode was immersed into the formulation. The value displayed on the pH meter screen was then recorded (8).

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**Viscosity**

The viscosity of the NLC gel samples was evaluated using a Brookfield viscometer to determine the consistency of the NLC gel system. Measuring viscosity is crucial because the viscosity value can be influenced by various factors, including the addition of other formulation components such as surfactants and gelling agents. Furthermore, the preparation technique of the NLC gel can also affect its viscosity. In NLC systems, viscosity values typically range from 32.5 to 2499.5 cPs. The standard viscosity range for a well-formulated gel preparation is between 2000 and 4000 cPs (12).

**Particle Size and Polydispersity Index (PDI)**

Particle size was measured using a Microtrac Particle Size Analyzer (PSA). The polydispersity index (PDI) was employed to evaluate the uniformity of particle size distribution within the nanoparticles. PDI values range from 0 to 1, where values closer to 0 indicate a narrow and homogeneous distribution with minimal aggregation, while values approaching 1 reflect broad size distribution and potential particle aggregation. For Nanostructured Lipid Carrier (NLC) systems, the optimal particle size typically ranges between 10 and 1000 nm (13).

**Percent Entrapment Efficiency**

Entrapment efficiency (EE) is expressed as a percentage (%), representing the proportion of the drug successfully encapsulated within the nanoparticles relative to the initial amount of drug incorporated into the lipid phase of the Nanostructured Lipid Carrier (NLC) system. The encapsulation efficiency is calculated using the following formula (14).

$$\%Entrapment\ Efficiency = \frac{W\ total - W\ free}{W\ total} \text{ x } 100\%$$

**W total:** Mass of drug added to the formulation
**W free:** Mass of drug analyzed in the supernatant

**Interpretation of Percent Entrapment Efficiency**

Percent entrapment efficiency (EE) reflects the proportion of the active ingredient encapsulated within the lipid particles. EE is typically measured using the centrifugal ultrafiltration method, where the supernatant obtained after centrifugation is analyzed by UV-Vis spectrophotometry. Generally, lipophilic formulations exhibit EE values greater than 80%, whereas hydrophilic formulations show EE values exceeding 30% (15).

**Spreadability**

Spreadability of semi-solid formulations is inversely related to their viscosity; formulations with higher viscosity generally exhibit lower spreadability, and vice versa (16). Spreadability testing is conducted to evaluate the ability of a gel formulation to evenly spread over the skin surface (11). The standard spreadability range for a well-formulated gel is between 5 and 7 cm, determined by applying a round glass plate with a 150-gram weight (17).

## RESULT AND DISCUSSION

### Physicochemical Characterization of Minoxidil and Finasteride Combination NLC Gel

**Organoleptic Evaluation**

The results of the organoleptic evaluation showed that the NLC formulation containing a combination of minoxidil and finasteride appeared as a white, semi-solid preparation with a characteristic oily odor, as presented in Table 3. Meanwhile, the organoleptic characteristics of the NLC gel formulation containing minoxidil and finasteride are shown in Table 4, indicating a gel-like consistency, milky white color, and no detectable odor. The visual results of the organoleptic test are illustrated in Figure 1.

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**Table 3. Physicochemical Characterization of NLC Containing a Combination of Minoxidil and Finasteride**

| Physicochemical Parameters | R1 | R2 | R3 | Mean± SD |
|---|---|---|---|---|
| Organoleptic | Semi-solid, milky white color, characteristic oily odor | Semi-solid, milky white color, characteristic oily odor | Semi-solid, milky white color, characteristic oily odor | |
| pH | 6.28 | 6.28 | 6.26 | 6.28±0.01 |
| viskositas | 92.91 | 90.6 | 69.54 | 84.35±12.8 |
| ukuran partikel (µm) | 0.554 | 1.775 | 0.727 | 0.4861±0.28 |
| *polydispersity index* (PDI) | 0.42 | 0.651 | 0.1952 | 0.227±0.42 |
| %EE | 87.80% | 87.25% | 87.55% | 87.53%±0.002 |

**Table 4. Physicochemical Characterization of NLC Gel Containing a Combination of Minoxidil and Finasteride**

| Physicochemical Parameters | R1 | R2 | R3 | Mean ± SD |
|---|---|---|---|---|
| Organoleptic | Gel form, milky white color, odorless | Gel form, milky white color, odorless | Gel form, milky white color, odorless | |
| pH | 5.57 | 5.81 | 5.78 | 5.78 ± 0.02 |
| Viscosity (cPs) | 3500 | 3500 | 3500 | 3500 ± 0 |
| Spreadability (cm) | 6.4 | 6.5 | 6.4 | 6.43 ± 0.05 |

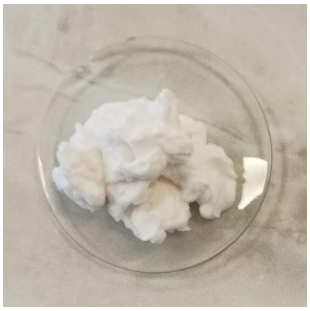

**Figure 1. Organoleptic Evaluation of the NLC Gel Formulatio**

**pH Measurement**

The pH measurement results indicated that the minoxidil and finasteride combination NLC had a pH in the range of 6.26–6.28, as presented in Table 3. For the NLC gel, a pH range of 5.57–5.81 was obtained, as shown in Table 4. These results fulfill the requirements for a good topical formulation, which specify a pH range of 4.5–6.5 (18).

**Viscosity**

Viscosity measurements were conducted in two stages: first, while the preparation was still in NLC form, and second, after the NLC was incorporated into the gel. The viscosity of the NLC was tested using a Brookfield Cone and Plate Viscometer with spindle no. 41 at a speed of 10 rpm. Conversely, the viscosity of the NLC gel was measured using a 'Rion' Viscotester VT-04F with spindle no. 3 at a speed of 62.5 rpm. For the NLC viscosity test, results in the range of 69.54–91.91 cP were obtained, as presented in Table 3. In the NLC gel viscosity measurement, a result of 3500 cP was observed, as shown in Table 4. These findings demonstrate that the viscosity, both for the NLC and after its incorporation into the NLC gel, met the existing viscosity requirements. Specifically, the optimal viscosity range for NLC formulations is between 32.5 and 2499.5 cPs (3), and for NLC gel preparations, it is between 2000 and 4000 cPs (12).

**Particle Size and Polydispersity Index (PDI)**

Particle size and polydispersity index (PDI) measurements were carried out using a Microtrac Particle Size Analyzer on the NLC formulation containing a combination of minoxidil and finasteride. Particle size is one of the most critical parameters in NLC systems, as it determines the homogeneity of the formulation and influences drug entrapment, release, penetration, and overall stability (8). The polydispersity index (PDI) serves as an indicator of the nanoparticle size distribution.

The results from three replications showed an average particle size of 486.1 ± 0.280 nm and an average PDI of 0.422 ± 0.227, as shown in Table 3. These values meet the criteria for an ideal NLC system, with particle sizes falling within the optimal range of 10–1000 nm and PDI values between 0 and 1. A PDI value close to 0 indicates a uniform nanoparticle size distribution with minimal aggregation. In contrast, a PDI approaching 1 reflects a broader particle size distribution and a greater tendency for aggregation (13).

**Percent Entrapment Efficiency Test**

The determination of entrapment efficiency is a critical characterization technique used to evaluate the percentage of active pharmaceutical ingredients encapsulated within the NLC system (8). This measurement was performed using centrifugation followed by UV-Vis spectrophotometric analysis. In brief, 0.15 grams of the NLC formulation containing minoxidil and finasteride was dissolved in phosphate buffer (pH 6.0) to a final volume of 15 mL. The mixture was centrifuged at 6000 rpm for 45 minutes (19). During this process, the lipid matrix separated from the supernatant, which contained unencapsulated minoxidil and finasteride.

The resulting supernatant was analyzed using a UV-Vis spectrophotometer at 287 nm for minoxidil and 210 nm for finasteride. The absorbance values obtained were plotted against the respective standard calibration curves for each drug. The entrapment efficiency of the minoxidil–finasteride NLC system was found to be 87.53% ± 0.002, as shown in Table 3. This result indicates that the NLC system successfully achieved a high entrapment efficiency, exceeding 80%, in accordance with the desired formulation specifications.

**Spreadability**

The spreadability test is a critical parameter in evaluating the quality of gel formulations. The extent of spread directly correlates with the formulation's effectiveness in delivering therapeutic agents to the skin. Greater spreadability indicates a superior ability to evenly distribute the active ingredients across the skin surface, thereby enhancing therapeutic outcomes (20).

In this study, spreadability measurements from three replications of the minoxidil–finasteride NLC gel formulation yielded an average value of 6.4 ± 0.05 cm, as shown in Table 4. These results confirm that the spreadability falls within the acceptable range of 5–7 cm, meeting the required specification for a well-formulated gel (17).

**Application of Minoxidil and Finasteride Combination NLC Gel in Prospective Hajj Pilgrims**

Prospective Hajj pilgrims encounter unique physical and environmental challenges during their pilgrimage in the Holy Land. One common health concern, particularly among men, is androgenic alopecia. In this context, topical therapy utilizing a Nanostructured Lipid Carrier (NLC) gel containing minoxidil and finasteride offers an innovative solution to enhance the stability, efficacy, and convenience of treatment throughout the Hajj journey. The NLC gel formulation provides several advantages, including improved penetration of active ingredients into the scalp, sustained release of the drugs, and protection against degradation due to high ambient temperatures (6). This is especially relevant, as temperatures in Saudi Arabia during the Hajj season can reach 40–50°C, which may accelerate the degradation of conventional formulations.

The use of this NLC gel is recommended as a preparatory measure prior to departure. The optimal initiation period is at least 3 to 6 months before the pilgrimage. Studies have shown that minoxidil requires 3–6 months to produce noticeable hair growth, while finasteride needs a minimum of 3 months to exert its maximum inhibitory effect on dihydrotestosterone (DHT), the main cause of androgenic alopecia. The gel can be applied twice daily—once in the morning and once at night. Morning application is recommended after showering, when the scalp is clean and dry, while evening application should be done before bedtime to optimize the drug's action during the skin's regenerative phase. Initiating use of the minoxidil–finasteride NLC gel prior to travel allows pilgrims to optimize scalp and hair health, ensuring that use during the pilgrimage is for maintenance purposes only, rather than for initiating treatment. This contributes to greater comfort and confidence in performing the pilgrimage under optimal physical conditions.

During the pilgrimage, continued application is recommended; however, the timing should be adjusted to accommodate religious activities. Ideally, the gel should be applied after the morning shower or at night before sleep. Application should be avoided prior to activities that induce excessive sweating, such as Tawaf or Sai, as this may reduce the product's effectiveness. Additionally, extreme weather conditions, particularly high temperatures, may cause irritation in individuals with sensitive scalps. In such cases, product use should be discontinued immediately.

## CONCLUSION

Based on the research findings, the Nanostructured Lipid Carrier (NLC) gel formulation combining minoxidil and finasteride utilizing monostearin as the solid lipid and Miglyol 808 as the liquid lipid in an 8:2 ratio fulfilled the organoleptic and physicochemical requirements in accordance with applicable pharmaceutical standards. The formulation exhibited a slightly fluid gel consistency, white appearance, a characteristic oily odor, and

demonstrated homogeneity. The average particle size was 486.1 nm, with a Polydispersity Index (PDI) of 0.422, indicating an adequately uniform particle distribution. The pH value of 5.78 ± 0.02 was within the physiological range of human skin (pH 4.5–6.5), supporting the chemical stability of the active pharmaceutical ingredients. Although the measured viscosity was 1500 cPs—below the ideal topical range of 2000–4000 cPs—it remained acceptable for dermal application. The entrapment efficiency reached 87.53%, surpassing the minimum acceptable threshold of 80%, while the spreadability of 6.4 cm fell within the optimal range of 5–7 cm. Overall, the formulation exhibits favorable physicochemical characteristics for topical delivery and demonstrates potential to improve the dermal bioavailability of both minoxidil and finasteride.

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